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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,992	03/31/2004	Ruvin Deych	56229-153 (ANA-248)	8176
7590	11/30/2005		EXAMINER	
Toby H. Kusmer McDermott, Will & Emery 28 State Street Boston, MA 02109			HO, ALLEN C	
			ART UNIT	PAPER NUMBER
				2882

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

H.A

Office Action Summary	Application No.	Applicant(s)	
	10/814,992	DEYCH ET AL.	
	Examiner	Art Unit	
	Allen C. Ho	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 31 March 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09Aug2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

Paragraph [0050], line 7, "□□" should be replaced.

Appropriate correction is required.

Claim Objections

2. Claim 1 is objected to because of the following informalities:

- (1) Line 7, --operating-- should be inserted between "first" and "voltage";
- (2) Line 13, --operating-- should be inserted between "second" and "voltage".

Appropriate correction is required.

3. Claim 16 is objected to because of the following informalities:

- (1) Line 9, " Δ_{t1} " should be replaced by $--\Delta t_1--$;
- (2) Line 10, " Δ_{t2} " should be replaced by $--\Delta t_2--$;
- (3) Line 12, --operating-- should be inserted between "first" and "voltage";
- (4) Line 21, --operating-- should be inserted between "second" and "voltage".

Appropriate correction is required.

4. Claim 18 is objected to because of the following informalities:

Claim 18 recites the limitations "said electron source" and "said x-ray target". There is insufficient antecedent basis for these limitations in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 2, 4-17, and 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining operating voltage between a cathode and an x-ray emissive target, does not reasonably provide enablement for determining the operating voltage for other components in an x-ray apparatus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification only discloses determining and setting operating voltages between a cathode and an anode in an x-ray tube. The specification does not enable any person skilled in the art to determine operating voltage for other components, such as an x-ray detector or a controller.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites "said processor is further configured to determine the optimal values of one or more x-ray exposure parameters, and wherein said x-ray exposure parameters include at

least one of operating voltage (kVp), current (mA), and size of focal spot;" However, claim 16 claims a processor configured to calculate an optimal operating voltage. Therefore, operating voltage should be deleted from this list of x-ray exposure parameters.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 7, 8, 11, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Unger *et al.* (U. S. Patent No. 6,501,819 B2).

With regard to claim 1, Unger *et al.* disclosed a method for optimizing radiographic image quality by irradiating the object with x-rays from an x-ray apparatus during an initial period of an x-ray exposure, the method comprising:

- A. determining a first operating voltage level kVp_0 for initial operation of the x-ray apparatus (default exposure settings, column 4, lines 7-14);
- B. during a first sampling interval Δt_1 in the beginning of the x-ray exposure period, operating the x-ray apparatus at the first voltage level kVp_0 and using one or more sensors to detect x-rays that have passed through at least a portion of the object during the interval Δt_1 (first image, column 4, lines 7-14);
- C. after the first sampling interval Δt_1 , processing the output signals from the sensors to determine a second operating voltage level kVp_1 (column 5, lines 22-33);

D. during a second sampling interval Δt_2 , operating the x-ray apparatus at the second voltage level kVp_1 and using the sensors to detect x-rays that have passed through at least a portion of the object during the interval Δt_2 (second image, column 5, lines 34-36);

E. after the second sampling interval Δt_2 , processing the sensor output signals to determine an optimal value kVp_2 for the operating voltage level, and setting the operating voltage level of the x-ray apparatus to the optimal value kVp_2 for the remainder of the x-ray exposure period (adjusting exposure settings of 3rd image based on 2nd image, column 8, lines 25-27).

With regard to claim 2, Unger *et al.* disclosed a method in accordance with claim 1, wherein the x-ray apparatus comprises an x-ray source (required to produce x-rays).

With regard to claim 7, Unger *et al.* disclosed a method in accordance with claim 1, wherein the object comprises anatomical tissue of a patient, and wherein the optimal value of the operating voltage are chosen so that the patient's exposure is substantially minimized when the x-ray apparatus is operated at the optimal value (column 8, line 67 - column 9, line 1).

With regard to claim 8, Unger *et al.* disclosed a method in accordance with claim 2, wherein the x-ray imaging system comprises a flat panel detector (220).

With regard to claim 11, Unger *et al.* disclosed a method in accordance with claim 1, wherein the object comprises anatomical tissue of a patient, and further comprising the step of measuring the thickness of the tissue before the step of determining the first and second operating voltage levels (column 6, lines 15-26).

With regard to claim 15, Unger *et al.* disclosed a method in accordance with claim 1, wherein steps B and C are repeated for a plurality of n sampling intervals during which the x-ray

apparatus is operated at corresponding operating voltage levels, so that the optimal voltage level kVp_2 is determined based on sensor output signals generated while the x-ray apparatus was operated at voltage level kVp_1^n during a sampling interval Δt_1^n (column 8, lines 25-27).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger *et al.* (U. S. Patent No. 6,501,819 B2) as applied to claim 2 above, and further in view of Macovski (U. S. Patent No. 4,686,695).

With regard to claim 3, Unger *et al.* disclosed a method in accordance with claim 2. However, Unger *et al.* failed to teach that the operating voltage is the accelerating voltage between an electron source and an x-ray emissive target within the x-ray source.

Macovski disclosed an x-ray source comprising an electron source (12) and an x-ray emissive target (13). Macovski taught that the energy of the x-rays could be changed by changing the accelerating voltage between the electron source and the x-ray emissive target within the x-ray source (column 5, lines 40-46).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide an x-ray source having an electron source and an x-ray emissive

target and to adjust the accelerating voltage between the electron source and the x-ray emissive target, since a person would be motivated to change the energy of the x-rays.

With regard to claims 4 and 5, Unger *et al.* and Macovski disclosed a method in accordance with claim 3, further comprising determining the optimal values of additional x-ray exposure parameters comprising x-ray tube current (column 5, lines 30-33).

13. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Unger *et al.* (U. S. Patent No. 6,501,819 B2) as applied to claim 1 above.

With regard to claim 6, Unger *et al.* disclosed a method in accordance with claim 1. However, Unger *et al.* failed to teach that each sampling interval is relatively small compared to the x-ray exposure period.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to select sampling intervals that are relatively small compared with the x-ray exposure period, since a person would be motivated to reduce x-ray dose received by the patient.

Allowable Subject Matter

14. Claim 18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter:

With regard to claim 18, although the prior art discloses an x-ray apparatus comprising an x-ray source comprising an electron source and an x-ray target, an x-ray imaging system configured to receive x-rays that have been emitted from the x-ray source and that have passed

through the object and to generate an image of the object from the received x-rays, and a controller configured to adjust the accelerating voltage between the electron source and the x-ray target in the x-ray source, it fails to teach or fairly suggest that the x-ray apparatus further comprises one or more sensors disposed between the object and the x-ray imaging system, the sensors being configured to detect x-rays and to generate output signals representative of the attenuated intensity of the detected x-rays, and a processor configured to determine operating voltage levels by processing the output signals generated by the sensors as claimed.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- (1) Green *et al.* (U. S. Patent No. 6,768,784 B1) disclosed x-ray image enhancement.
- (2) Alving *et al.* (U. S. Patent No. 6,594,339 B1) disclosed an x-ray examination apparatus with exposure control.
- (3) Meulenbrugge (U. S. Patent No. 6,442,238 B2) disclosed sensors (18) positioned between an x-ray imaging system (8) and an object (9).
- (4) Joosten (U. S. Patent No. 6,330,302 B1) disclosed method and device for forming an image of an object from plurality of images.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allen C. Ho whose telephone number is (571) 272-2491. The examiner can normally be reached on Monday - Friday from 8:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward J. Glick can be reached at (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Allen C. Ho
Primary Examiner
Art Unit 2882

23 November 2005